



European Health Data Space

Game changer in health
data sharing

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WHY?

Lesson learned from COVID-19 pandemic

(lack of standardized health data, low ability to react to public threat at pan-EU level)

Member states creates their own eHealth systems without interoperability and standardization

(impossible cross-border sharing)

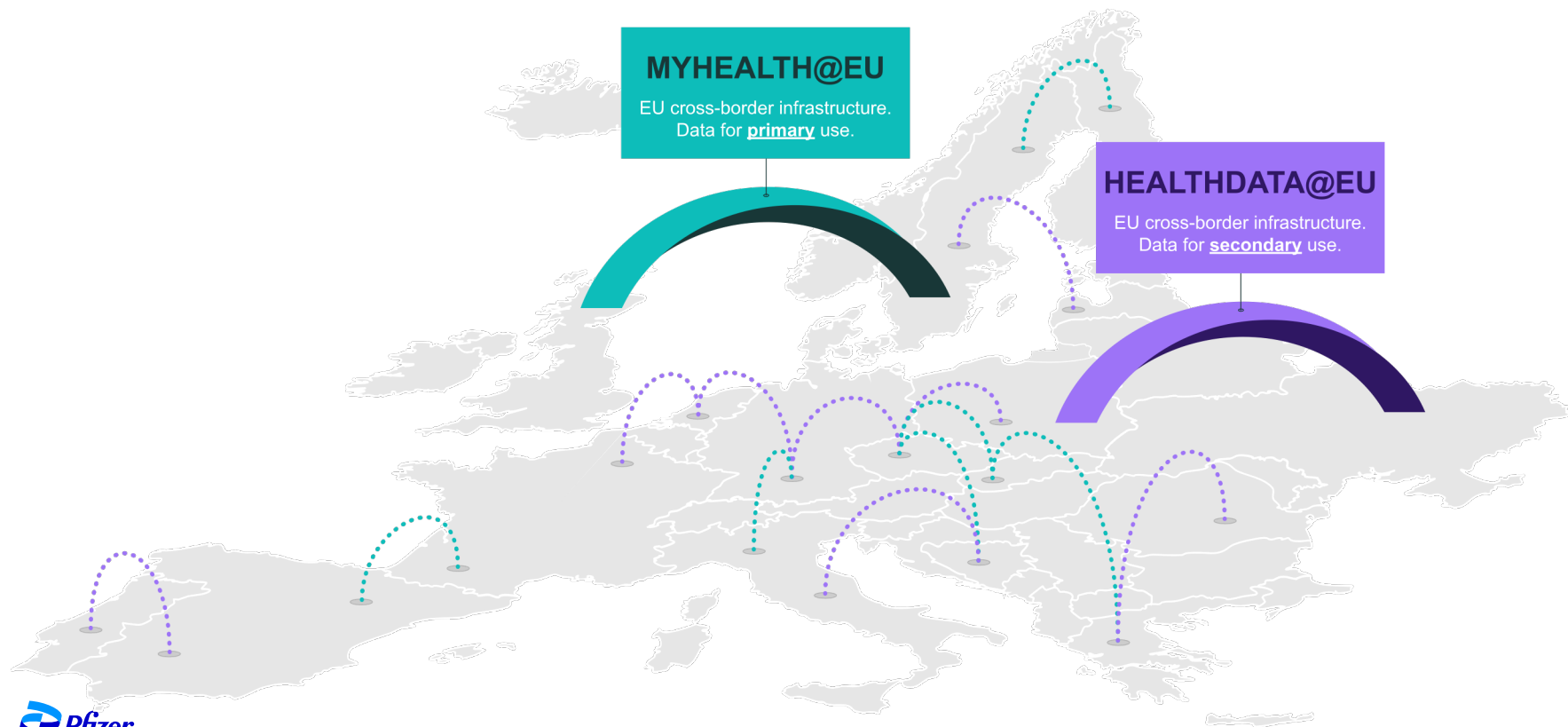
Support citizen's free movement with free movement of their primary el. health data

(single market for electronic health record systems)

Excessive protection of health data in member states

(EC Report on application of GDPR, 2021)

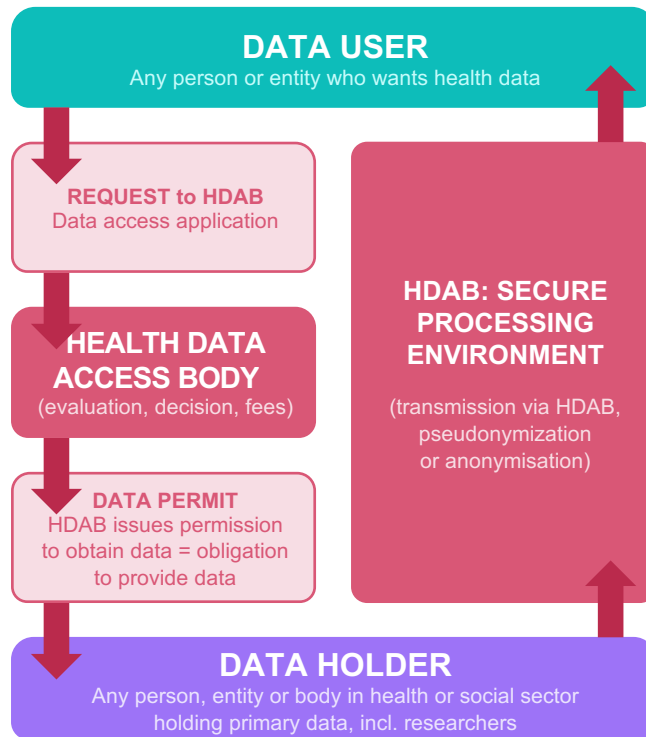
EUROPEAN HEALTH DATA SPACE



HEALTH DATA FOR SECONDARY USE

15 CATEGORIES of data TO BE SHARED (as anonymous, pseudonymous)

- EHR
- Data impacting health
- Pathogen genomic data
- Administrative data
- Genetic, genomic and proteomic data;
- Wellness and health apps.
- Identif. data on HCP
- Public health registries
- Specific disease registries, Medicines registries
- Data from clinical trials
- Data from MD
- Researches, surveys
- Biobanks and databases
- Status data relevant to health (education, insurance, behaviour)
- Corrections, annotations...



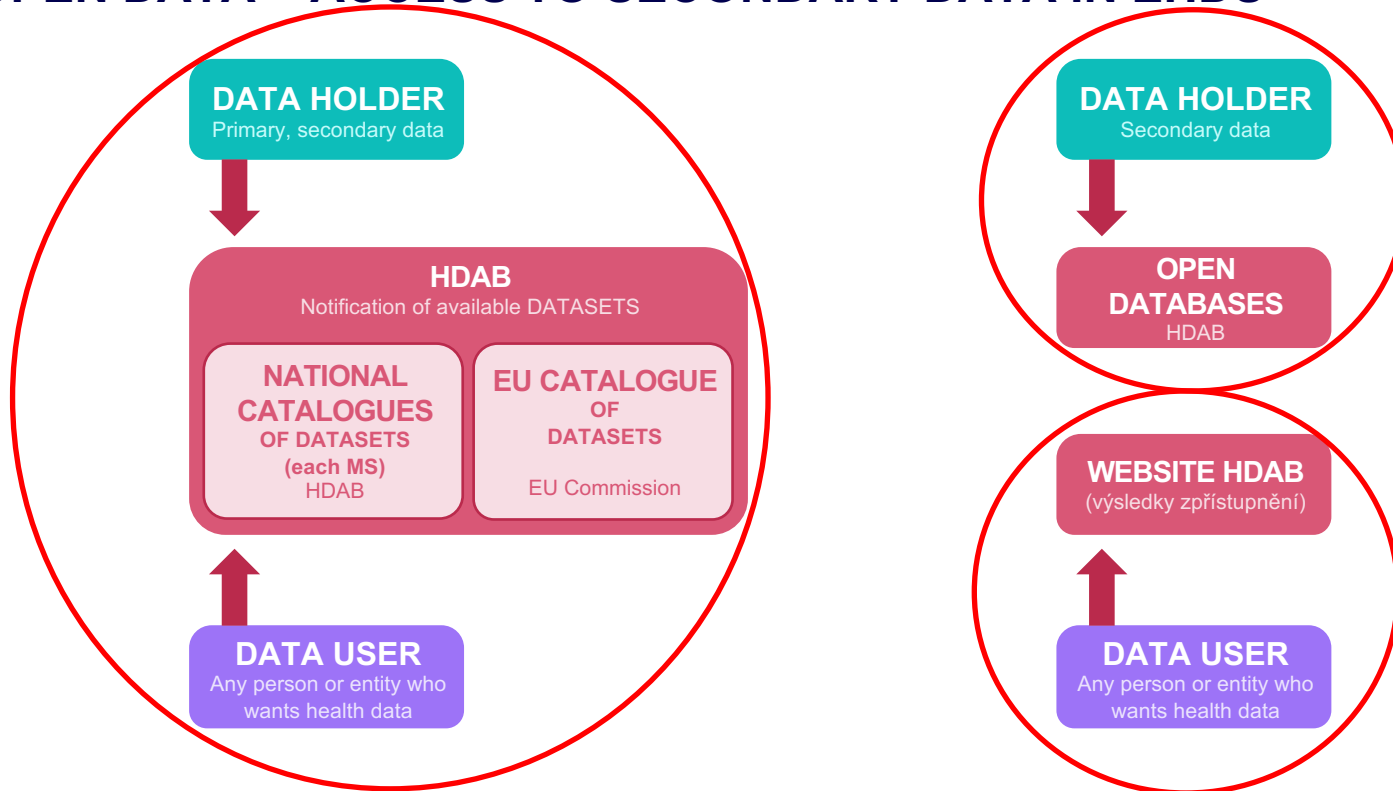
PURPOSES ALLOWED (8)

- Public interest, cross-border threat
- Support EU institutions
- Statistics
- Education
- Scientific research
- Developing health products, medicines and medical devices
- Training and testing of AI algorithms
- Provision of personalized healthcare

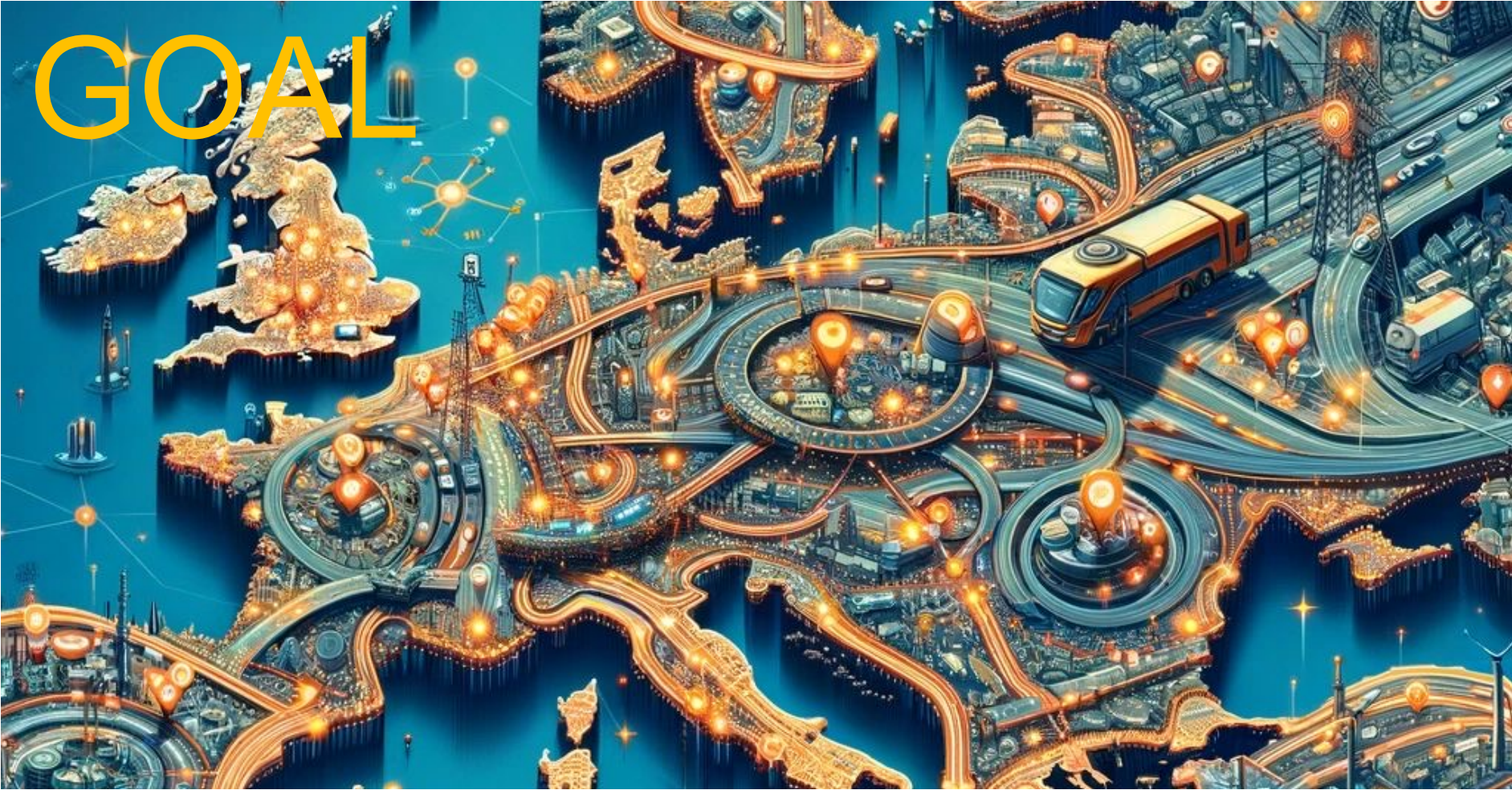
PURPOSES PROHIBITED (5)

- Taking decisions detrimental to patient
- Excluding patient from insurance...
- Advertisement or marketing toward HCP, HCP, patients
- Provide access to data to 3rd party (not in permit)
- Developing harmful products or services (drugs, alcohol, tobacco...)

OPEN DATA + ACCESS TO SECONDARY DATA IN EHDS



GOAL





Recommendations

- **FOLLOW CLOSELY** the **EHDS** and its development.
- **YOU are DATA HOLDER.** Therefore, be aware of duties for DATA HOLDER.
- **MAKE SURE YOUR DATA** privacy systems, data transmission systems, data storage systems and contractual provisions **ARE ALIGNED WITH EHDS.**
- **BE AWARE OF PATIENTS' RIGHTS.**
- EHDS is highly ambitious proposal with far-reaching consequences into the systems of all stakeholders relevant to health data (primary and secondary). **DEFINE YOUR OWN ROLE.**
- **ADVOCATE FOR DIRECT ACCESS OF CROS INTO THE EHR** (the clinical trial part)????

Status quo

ADOPTION

- Currently, the Council of EU and Eur. Parliament are running a „trialogues“
- Efforts to adopt the EHDS before June 2024
- Any provision might change during the trialogues – need to wait for adopted version for evaluating potential impact and timelines

PROTECTION OF IPR

- IPR – intelectual property rights (patents, trade secrets)
- Concerning obligation for data holder to provide also IPR protected data
- BUT „*take all specific measures to preserve confidentiality*“ is not satisfactory solution
- Data holder should have the final right to refuse sharing the IPR protected data

OPT-OUT from data for secondary use

- Opt-out is not a GDPR' requirement
- Opt-out mechanism might jeopardise future innovations (incl. clinical trials) and weaken the principal value of health data for secondary purpose
- Member state-based approach is risky (differences between MS)



Thank you